

Amendments to the Drawings

The enclosed replacement sheet of drawings includes one change to figure 11. The reference character 230 has been removed from the drawing figure since it was not referenced in the specification.

REMARKS

The information disclosure statement filed on 1/16/04 has been indicated to be noncompliant with 37 CFR 1.98(a)(2) in that legible copies of each cited foreign patent document have not been provided. In response, a Supplemental Information Disclosure Statement will be submitted herewith to supply the missing copies.

The drawings have been objected to as failing to comply with 37 CFR 1.84(p)(5) because drawing figure 11 includes a character (230) not mentioned in the specification. In response, drawing figure 11 has been amended herein to remove the character 230. A replacement drawing sheet is submitted herewith.

The specification has been objected to because of informalities in the first paragraph on page 1 of the specification. In response, the specification has been amended herein to correct the informalities noted by the Examiner.

Claims 1-47 have been objected to because of informalities in the recitation of "head" in several claims which was not preceded by -- suction --. In response, all claims have been reviewed and corrective amendments have been made in claims 1, 4, 5, 12, 14, 19, 23, 30, 34, 40, 46 and 47.

1, 8 10, and 11 have been rejected under 35 U.S.C. 102(e) as being anticipated by Snow (6936001). In response, the applicants respectfully traverse the rejection. The Snow reference discloses a heart stabilizer for use in minimally invasive heart surgery. The heart stabilizer includes a pair of paddles connected to a vacuum source and a linkage or shaft connected to the paddles by a wrist which includes a gear rack driven by turning shafts that allows the paddles to be drawn inwardly in order to insert them through a port or small incision in the chest cavity without otherwise changing the position of the paddles. Once inside the chest, the paddles are extended outward by remote operation and the paddles are placed against the heart to create an operating space between the paddles. The purpose of this device is not to change the position of the heart but rather to contact the beating heart and limit the movement of a small area of heart tissue between the paddles so that a surgical procedure such as the suturing of a vein graft can be performed on that small space. By contrast, the applicants' invention is for a heart

positioning device which permits the heart to be moved from a physiological orientation to a non-physiological orientation in order to improve surgical access to a portion of the heart. In order to make the differences between the teachings of Snow and the applicants' invention explicit, independent claim 1 has been amended in the preamble to state the purpose of the device and also to recite in the body of the claim "a handle coupled to a proximal end of the shaft for remote manipulation of the position of the suction head to effect movement of the heart to a non-physiological orientation." Support for this amendment can be found at page 16, lines 4-6 and page 31, lines 10-14. Because of the differences between the intended purpose of the Snow device and the intended purpose of applicants' device, the structure of the devices is quite different. As set forth in independent claim 1, the suction head of applicants' device is a resilient, flexible suction head. There is no mention in Snow of either resilience or flexibility as being a property of the paddles. In fact, the intended purpose of the Snow device to stabilize a portion of the heart for surgical intervention would require the use of relatively rigid materials that can resist the movement of the beating heart. Snow achieves a small size for insertion of the paddles by a mechanical system that draws the paddles inwardly. This can be achieved even if the paddles are quite rigid. By contrast, the applicants' positioning device benefits from a resilient material that can be compressed during the procedure (especially as it is introduced through a small incision or port) and then return to its original shape. The applicants' positioning device also benefits from the use of a flexible material that can engage and conform to a particular surface of the beating heart as it is being repositioned. To make this distinction more clearly, independent claim 1 has been amended to recite "...a suction head comprising a flexible, resilient material that may be compressed and resiliently return to its original shape and may flex to permit the suction head to engage and conform to a target tissue on the surface of a heart..." Support for this amendment can be found at the first full paragraph of page 23. An additional distinguishing feature of the applicants' invention is in the movement of the suction head with respect to the shaft. In the Snow reference, the end effector is attached to the shaft by means of universal joints that can be manually adjusted to hold the paddles at a given angle with respect to the shaft. There is no provision for remotely adjusting the angle since the position of the paddles with respect to the shaft is undisturbed as the

paddles are driven inwardly or outwardly. (See Snow Col 4, lines 1-3.) By contrast, the applicants' invention as recited in claim 1 requires a remote means for changing the position of the suction head with respect to the shaft from an aligned to an unaligned condition. To make this clearer, claim 1 has been amended to recite a movable joint coupling the suction head with the shaft and "means on a proximal portion of the heart positioning device for remotely bending the movable joint from a first position in which the suction head is axially aligned with the shaft to a second, position in which the suction head is axially unaligned with the shaft." Such a remote means for changing the angular position of the suction head with respect to the shaft by bending a movable joint is not found in Snow. Support for this amendment can be found in the paragraph beginning on page 29 of the specification. Claim 8 has been canceled by amendment herein. For these reasons, the rejection of claims 1, 8 10, and 11 under 35 U.S.C. 102(e) should be withdrawn.

Claim 2 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Spence et al. (6019722). In response, the applicants respectfully traverse the rejection. The absence of motivation to combine these two references as the examiner proposes is quite apparent. In the applicants' remarks above it was pointed out that the Snow reference teaches a device and method for making a limited area on a beating heart still. It does not teach a device and method for moving the heart. By contrast, the applicants' invention relates to a device and method for moving the heart to a non-physiological position. The rejection asserts that a person skilled in the art looking at the Snow reference would choose to make alterations to it that would change it from its intended purpose to keep an area of tissue still and instead make it into a device and method for making the heart move to a non-physiological orientation. The applicants' respectfully disagree. The absence of any motivation in Snow to make this combination is apparent because the intended result of the combination would be the opposite of the intended purpose of Snow. Further, it is unclear how the device in Snow could be specifically combined with the device in Spence et al. The rejection apparently suggests that the paddles of Snow will be replaced by the suction cup and legs of Spence et al. If so, how will the gear rack of Snow be coupled to the suction cup to reduce its diameter as it is introduced through a port or incision? Also, by replacing the paddles

with the suction cup, the surgical space between the paddles would be obscured by the suction cup. Clearly, the intended purpose of the device in Snow would be impaired by the addition of the suction cup of Spence et al. Moreover, even if the references could be profitably combined, Spence et al. also fails to disclose a positioning device having legs as set forth in the applicants' claim 2. In particular, the applicants' specification at page 22, first full paragraph discusses the structure of the tissue-engaging head of figures 6a-f that may comprise legs or lobes. The legs or lobes comprise rounded projections extending from a more central portion of the suction head, not additional independent suction cups on the ends of projecting arms as disclosed by Spence et al. In order to clarify what the applicants mean by "legs" as set forth in claim 2 and to more clearly distinguish the applicants' invention from the disclosure of Spence et al., the applicants have amended claim 2 and other claims containing the term "legs" to instead recite -- lobes --. Support for this amendment can be found in the paragraph beginning on page 22. For these reasons, withdrawal of the rejection under 35 U.S.C. 103(e) is respectfully requested.

Claims 3-7, 12, 14-19 and 21-22 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Daniel, et al. (6174307). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with respect to the inapplicability of the Snow reference to the applicants' inventions are also pertinent to this rejection and are incorporated herein by reference. Neither Snow nor Daniel et al. disclose a heart positioning device set forth in the applicants' claims. As discussed above, the applicants' claims, including the claims which are the subject of this rejection, have been amended to recite that the device is intended and constructed to effect movement of the heart to a non-physiological orientation. Daniel, et al. discloses a surgical scope device which includes a shaft having a lumen with a cup member at a distal end and internal to the lumen are devices for observing and treating tissue such as heart tissue. For example visualization can be provided through the lumen order to guide the device toward a target heart tissue where the cup member is pressed against the heart tissue to stabilize the device with respect to the beating heart tissue to be treated. A laser or other device inserted within the lumen of the device can then provide energy to treat the tissue. Thus, observation and treatment

with this device occurs within the space circumscribed by the cup member and the cup provides stabilization, not repositioning of the target tissue. The rejection asserts that a person skilled in the art looking at the Snow reference would choose to make alterations to it that would change it from its intended purpose, which is to keep an area of tissue still. The isolated structures extracted from the Daniel, et al. reference also do not purport to reposition heart tissue but rather to stabilize tissue of a beating heart with respect to a medical treatment device. The person skilled in the art would not obviously combine two references that teach making the heart still in order to fashion a device and method for making the heart move. The absence of any motivation in Snow or Daniel, et al. to make this combination is apparent. Further, it is unclear how the device in Snow could be specifically combined with the device in Daniel, et al. The rejection apparently suggests that the paddles of Snow will be replaced by the cup member of Daniel, et al. If so, how will the gear rack of Snow be coupled to the cup member of Daniel to reduce its diameter as it is introduced through a port or incision? Also, by replacing the paddles with the cup member, the surgical space between the paddles would be obscured by the cup and the surgeon would be unable to work within that space. Clearly, the intended purpose of the device in Snow would be impaired by the addition of the cup member of Daniel, et al. Further, claims 3-6 depend from claim 1 which has been amended to recite a movable joint coupling the suction head with the shaft and “means on a proximal portion of the heart positioning device for remotely bending the movable joint from a first position in which the suction head is axially aligned with the shaft to a second, position in which the suction head is axially unaligned with the shaft.” Such a remote means for changing the angular position of the suction head with respect to the shaft by bending a movable joint is not found in Snow or Daniel, et al. Further, independent claim 12 (and also dependent claims 14, and 16-18) have been amended to recite a suction head having at least three lobes comprising a flexible, resilient material that are drawn against one another by an advancing sleeve and also slideably released from capture with the sleeve by advancing the suction head distally from the sleeve. Such a multi-lobed suction head is not found in Snow or Daniel, et al. Additionally, independent claim 19 (and also dependent claim 22) has been amended to recite a suction head having at least three lobes comprising a flexible, resilient material. Such a multi-lobed suction head is not found in

Snow or Daniel, et al. Claims 7, 20 and 21 have been cancelled by amendment herein. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claim 9 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Cohen (5336252). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with respect to the inapplicability of the Snow reference to the applicants' inventions are also pertinent to this rejection. Neither Snow nor Cohen teach a heart positioning device as set forth in the applicants' claims. As discussed above, the applicants' claims, including the claims which are the subject of this rejection, have been amended to recite that the device is intended and constructed to effect movement of the heart to a non-physiological orientation. Neither Snow nor Cohen discloses a device for repositioning the heart to a non-physiological orientation. Again, this rejection asserts that a person skilled in the art looking at the Snow reference would choose to make alterations to it that would change it from its intended purpose, which is to keep an area of tissue still. The isolated structures extracted from the Cohen reference also do not purport to reposition heart tissue. The person skilled in the art would not obviously combine such two references in order to fashion a device and method for making the heart change its position. The absence of any motivation in Snow or Cohen to make this combination is apparent. Also, it is unclear how the stabilization device in Snow can be profitably combined with the device in Cohen while preserving the intended purpose of the Snow device. The examiner is apparently suggesting that a portion of the shaft of the device of Snow securing the head and paddle assembly will be replaced by a flexible wire guide spring structure as shown in figure 15 of Cohen. However, if such a spring is used, the internal drive shafts may bind on the spring as it flexes and prevent their operation. Clearly, the intended purpose of the device in Snow would be impaired by the addition of the wire guide spring of Cohen. Further, the examiner suggests that the motivation for the addition of a spring to the device of Snow is to provide a spring force that would bias the position of the head assembly on the shaft in a particular direction. However, in the Snow reference, the end effector is attached to the shaft by means of universal joints that can be manually adjusted to hold the paddles at a given angle with respect to the shaft and which then remain in that position as the paddles are moved inward or outward. (See Snow Col 4, lines 1-3.)

Applying a spring bias to this arrangement would impair the ability of the operator to manually set the desired position of the end effector. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claims 13 and 20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Daniel, et al. (6174307) as applied to claims 12 and 19 and further in view of Paolitto, et al.. (6517563). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with respect to the inapplicability of the Snow reference and the lack of motivation to combine Snow and Daniel, et al. are also pertinent with respect to this rejection and are incorporated by reference herein. The rejection points to the apex-contacting members of figures 11, 12A and 12B as teaching a suction head with at least three resilient legs. As set forth above, amendments to the claims have been made which clarify what the applicants mean by "legs" as set forth in the claims. The term – lobes – is now used instead of "legs" to describe the construction of the suction head wherever the term "legs" appeared in the claims. The only apex-contacting member in Paolitto, et al. that looks like it may have lobes is figure 12B. However, that embodiment is disclosed to have rigid finger-like protrusions. (See Paolitto, et al. at column 22, lines 27-29.) Since the applicants' claims are limited to a suction head that has flexible and resilient lobes, not rigid lobes, the Paolitto, et al. reference fails to provide the lobes as set forth in the applicants' claims. It should be noted that claims 13 and 20 have been canceled herein in favor of other claims reciting "lobes." For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claims 23 and 30-33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Boyd, et al. (5799661). In response, the applicants respectfully traverse the rejection. The applicants' remarks above with respect to the inapplicability of the Snow reference are also pertinent with respect to this rejection. The rejection indicates that the system and method similar to that of Snow could be used with the method of non-physiological positioning of the heart similar to that disclosed by Boyd, et al. However, since the Snow device is intended and constructed to merely stabilize the surgical site, and not to reposition the heart to a non-physiological position, the rejection seems to be saying that the device shown in Boyd

would be used in addition to the device of Snow in order to perform the procedure. This is not the applicants' claim. The applicant is claiming in claims 23 and 30-33 a method employing a single device for repositioning the heart to a non-physiological position in which a flexible, resilient suction head is introduced into the chest cavity of a patient by placing it in a compressed condition and then changed in position from a first axially aligned position with the shaft to a second, unaligned position by manipulating a movable joint from outside the chest cavity of the patient while the suction head is within the chest cavity. This is not disclosed in either Snow or Boyd, et al. Further, the combining of method steps for a stabilizer device with the method steps for a positioner device is inherently in conflict because the two devices have entirely different functions. The person skilled in the art would not obviously select a method intended to stabilize the position of tissue in order to move tissue or a method intended to move tissue in order to stabilize tissue. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claim 24 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Boyd, et al. (5799661) as applied to claim 23 above and further in view of Paolitto, et al. (6517563). In response, the applicants respectfully traverse the rejection. The remarks set forth above with respect to the combination of the methods of the Snow and Boyd, et al. references are also pertinent to the combination of references here as are the remarks above with respect to Paolitto, et al. Those remarks are incorporated herein by reference. The examiner has cited Paolitto, et al. as teaching a method of using a suction head with at least three legs and has referenced the disclosure relating to figures 11, 12A and 12B. Claim 24 has been amended to recite "lobes" rather than legs and that the step of introducing the suction head includes compressing at least three resilient lobes of the suction head such that the lobes are drawn against one another. Paolitto, et al. does not disclose such a method since the only embodiment that appears to have lobes, figure 12B, is indicated to have rigid, finger-like protrusions that are not resilient and therefore could not be compressed and drawn together for insertion as in the applicants' method. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claims 25-29, 34 36-40 and 42-47 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Boyd, et al. (5799307) as applied to claim 23 above, and further in view of Daniel, et al. (6174307). In response, the applicants respectfully traverse the rejection. The remarks set forth above with respect to the unsuitability of the combination of the methods of the Snow and Boyd, et al. references are also pertinent to the combination of references in this rejection and are incorporated herein by reference. Also the remarks set forth above with respect to the unsuitability of the combination of the device of Snow and Daniel, et al. are also pertinent to the combination of references in this rejection and are incorporated herein by reference. The addition of the Daniel, et al. reference in this rejection adds yet a third method to the two dissimilar methods of Snow and Boyd, et al. Daniel, et al. discloses the use of a surgical scope device which includes a shaft having a lumen with a cup member at a distal end and internal to the lumen are devices for observing and treating tissue such as heart tissue. A laser or other device inserted within the lumen of the device can then provide energy to treat the tissue. Thus, observation and treatment with this device occurs within the space circumscribed by the cup member and the cup provides stabilization, not repositioning of the target tissue. The rejection asserts that a person skilled in the art looking at the Snow reference would choose to change the method by combining some method steps from Boyd, et al. with would change it from its intended purpose, which is to keep an area of tissue still and also change Snow it from its paddle structure to a structure with the cup of Daniel, et al. which would then prevent surgical access to tissue to be treated. Given the greatly differing structure and intended purpose for the devices disclosed in the three references, the only way that the applicants' invention could be derived from the references is to use the applicants' claims as a template to direct the combination. This is impermissible hindsight reconstruction of the invention. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

Claims 35 and 41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Snow (6936001) in view of Boyd, et al. (5799307) and further in view of Daniel, et al. (6174307) as applied to claims 34 and 40, and further in view of Paolitto, et al. (6517563). In response, the applicants respectfully traverse the rejection. The remarks set forth above with respect to the unsuitability of the combination of the


methods of the Snow and Boyd, et al. references are also pertinent to the combination of references in this rejection and are incorporated herein by reference. Also the remarks set forth above with respect to the unsuitability of the combination of the device of Snow and Daniel, et al. are also pertinent to the combination of references in this rejection and are incorporated herein by reference. In addition, the remarks above regarding the unsuitability of the combination of Snow, Daniel, et al. and Paolitto, et al. references is also pertinent to the combination of references in this rejection and are incorporated herein by reference. The addition of the Paolitto, et al. reference in this rejection adds yet a fourth method and device to the dissimilar methods of Snow, Boyd, et al. and Daniel, et al. Also, as set forth above, this rejection is clearly the product of hindsight reconstruction of the applicants' invention. Moreover, also as set forth above, Paolitto, et al. fails to teach the aspect of applicants' device which employs at least three resilient lobes since Paolitto, et al. instead discloses rigid, finger-like protrusions that are not resilient. For these reasons, the rejection under 35 U.S.C. 103(a) should be withdrawn.

The applicants believe that the amendments and remarks set forth herein have obviated all grounds for rejection and objection set forth in the office action of September 7, 2006 and have placed the application in condition for allowance. Reconsideration and allowance of the application as amended is respectfully requested.

A request for a one (1) month extension of time under 37 CFR 1.136(c) is filed with this response. Please charge the fee for the submission of the one month extension of time to Deposit Account No. 13-2546.

Please charge any additional required fees or credit any overpayment to
Deposit Account No. 13-2546.

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